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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,293	08/24/2001	Emad S. Alnemri	480140.465	2539

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EXAMINER
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DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/04/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/939,293

Applicant(s)

ALNEMRI, EMAD S.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-33 and 36-51 is/are pending in the application.
- 4a) Of the above claim(s) 32,33,40-43 and 48-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-31,36-39 and 44-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 28-31, 36-39, 44-47 are being examined.

This application contains claims drawn to an invention nonelected with traverse in Paper No.11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following are the remaining rejections.

### **OBJECTION**

The amended claims 44-47 are objected to because claims 44-47 are identical to claims 36-39.

Claims 44-47 are objected to because they are drawn to the same composition as claims 36-39, respectively

Applicant is advised that should claims 36-39 be found allowable, claims 44-47 will be rejected under 35 U.S.C. 101 as being a substantial duplicate thereof, When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP 706.03(k).

### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE**

Rejection under 35 USC 112, first paragraph of claims 36-39, 44-47 pertaining to remains for reasons already of record in paper No.14.

Applicant argues that one could readily screen for the claimed peptides for their ability to bind to IAP or a BIR domain, using routine procedure.

Applicant argues that the existence of one or more inoperative species encompassed within a genus that may be unable to specifically bind to an IAP or BIR domain is insufficient to support an assertion of non-enablement.

Applicant's arguments set forth in paper No.15 have been considered but are not deemed to be persuasive for the following reasons:

The claims encompass any amino acid sequence of any length, provided it contains at least **any 7 contiguous amino acids** from 30 amino acids of the residues 56-85 of SEQ ID NO:19.

It is noted that there are 30 amino acids within the residues 56-85 of SEQ ID NO:19, and that only the first seven contiguous amino acids of residues 56-85 of SEQ ID NO:19 could bind to a BIR domain and promotes caspase activity.

Further, the number of possibilities of species of any length, that contain at least **any 7 contiguous amino acids** from 30 amino acids of the residues 56-85 of SEQ ID NO:19 is numerous, and one could not predict that they are operative, because they do not necessarily contain the first seven contiguous amino acids of residues 56-85 of SEQ ID NO:19.

Applicant has not shown how to make the claimed sequences of unknown structure and unknown function.

Therefore, it would be undue experimentation for one of skill in the art to practice the claimed invention.

## **REJECTION UNDER 35 USC 102(e), NEW REJECTION**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28-31, 36-39, 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002110851-A1.

The amended claims 28-31 now are drawn to an isolated peptide or polypeptide comprising an amino acid sequence of at least residues 56-62 of SEQ ID NO:19, wherein said peptide or polypeptide comprises less than 184 contiguous amino acid

residues derived from residues 56-239 of SEQ ID NO:19, and wherein said peptide or polypeptide is capable of specifically binding to at least BIR1/BIR2 domains.

The amended claims 36-39, 44-47 now are drawn to an isolated peptide or polypeptide comprising an amino acid sequence of at least residues 56-85 of SEQ ID NO:19, wherein said peptide or polypeptide comprises less than 184 contiguous amino acid residues derived from residues 56-239 of SEQ ID NO:19, and wherein said peptide or polypeptide is capable of specifically binding to at least BIR1/BIR2 domains.

US 2002110851-A1 teaches a partial pro-apoptotic sequence of 84 amino acids in length, wherein said sequence comprises an amino acid sequence that is 100% similar to residues 56-62, or 7 amino acids of residues 56-85 of SEQ ID NO:19, as shown by MPSRCH sequence similarity search (MPSRCH search report, 2003, us-09-939-293a-19-copy-56-62.rag, page 8 ).

US 2002110851-A1 also teaches a partial pro-apoptotic sequence of 29 amino acids in length, wherein said sequence comprises an amino acid sequence that is 100% similar to 9 amino acids of residues 56-85 of SEQ ID NO:19, as shown by MPSRCH sequence similarity search (MPSRCH search report, 2003, us-09-939-293a-19-copy-56-85.szlm30.rag, page 5-6)

The sequences taught by US 2002110851-A1 certainly comprises less than 184 contiguous amino acid residues derived from residues 56-239 of SEQ ID NO:19, because they have only 29 or 84 amino acids in length.

Thus the sequence taught by US 2002110851-A1 seems to be the same as the claimed sequences.

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The reference does not teach that the pro-apoptotic protein is a Smac peptide that binds to BIR1/BIR2 domains. However, the claimed peptide or polypeptide appears to be the same as the prior art amino acid sequence. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

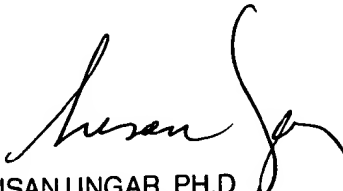
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

October 30, 2003



SUSAN UNGAR, PH.D  
PRIMARY EXAMINER